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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/830,095	04/23/2004	Seiichi Ono	8029/84010	7519
42798 7590 07/24/2008 FITCH, EVEN, TABIN & FLANNERY P. O. BOX 18415 WASHINGTON, DC 20036				
EXAMINER				
FITZGERALD, JOHN P				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/830,095

Applicant(s)

ONO, SEIICHI

Examiner

JOHN FITZGERALD

Art Unit

2856

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
4a) Of the above claim(s) 4-12, 14, 16 and 18-60 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☐ Claim(s) 1, 13, 15 and 17 is/are rejected.
7) ☒ Claim(s) 2 and 3 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 13 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,047,058 to Dvorsky et al. and US 6,295,873 to Condreva. Dvorsky et al. disclose a leak (extravasation) detector for detecting a liquid injected through a needle (50) into a blood vessel near the surface of a human body (see Fig. 1 below) including a pulse generating means (i.e. energy source for generating waves of electromagnetic radiation (x-ray, gamma ray) or ultrasound (i.e. sound/sonic) signals are emitted towards the human body and the subsequent reflected signals are detected/measured and then an imaging apparatus is used to display (i.e. warning result/indicator) the results to indicate the occurrence of a leak/extravasation. However, Dvorsky et al. do not expressly disclose waves emitted a predetermined wavelength; a interval measuring means to measure a time interval between the emission and reception/detection of the pulsed signals; a difference calculating means to calculate the difference between the measured time interval and a predetermined reference time interval; and a difference comparing means for comparing the difference with a predetermined acceptable range and thus issuing a leak notification/warning if exceeded (as recited in claim 1).
3. Condreva discloses an ultrasonic sensor and method of use for measuring the transit time (i.e. interval) of reflected/transmitted pulsed sound waves by a pulse generator (pulse generating means) (2) through a sample (or, "In the field of medicine, specific properties of bodily fluids can be monitored" (Condreva: col. 8, lines 36-37)), wherein a interval measuring means (i.e.

timing circuit/interval counter), representing small changes in the velocity of sound transmitted, over small time intervals to determine the presence of constituents in a sample (i.e. a change in composition/property of the sample to which the pulsed wave signals are transmitted through/reflected from); the transit time measured and compared to (i.e. difference calculating means, as recited in claim 1) a predetermined reference time (i.e. predetermined interval, as recited in claim 1), which is determined by a 'pre-calibration' procedure, thus determining the presence/change in the sample. Condreva further discloses an interval storing means (see Condreva, claim 6) for storing the predetermined transit/reference time. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the leak/extravasation detector disclosed by Dvorsky et al., by employing the technique of measuring the transit time of a pulsed acoustic/sound wave signal, as disclosed by Condreva, thus providing a system capable of operating in environments of extreme ranges of temperature, pressure and pH, is easily integrated in to existing systems, and does not require constant hands-on/manual adjustment by an operator (Condreva: col. 8, lines 43-62). In specific regards to the limitation of "at a predetermined wavelength" recited in instant claim 1, all signals/pulses generated by a signal generating system/apparatus in both the Dvorsky et al. and Condreva references inherently have specific wavelength(s) (typically predetermined based on what wavelength and/or frequency range the chosen signal is generated, i.e. visible/non-visible electromagnetic light range, sonic and/or ultrasonic, etc.), thus meeting this particular limitation of the claim. Furthermore, the choice of wavelength appears to be irrelevant to the function of the instant invention, since the 'transit time/interval' is only measured/determined, which is independent of the wavelength of the signal generated/reflected.

4. Claims 13, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,047,058 to Dvorsky et al. and US 6,295,873 to Condeva as applied to claim 1 above, and further in view of US 4,877,034 to Atkins et al. Dvorsky et al. and Condeva disclose a leak detector having all of the elements stated previously, including the employment of all types of signal waves including sonic and electromagnetic radiation, which includes light, and thus infrared radiation/rays, and in employment in the 'field of medicine.' Although Dvorsky et al. and Condeva do not specifically disclose the employment of an infrared rays (instant claim 13), (however, infrared rays are inherently included in the spectrum of 'electromagnetic radiation') at a specific wavelength (note: all types of waves, electromagnetic, sonic, etc. inherently have a specific or range of wavelengths and/or frequencies, as pointed out by the Examiner in paragraph 4 above) through a particular organ of a human body (instant claim 15), they do claim that the device can be employed in the field of medicine, and it is well known in the art that ultrasound devices are employed in the medical field for examining internal organs of humans. Atkins et al. disclose a leak detector employing infrared rays exposing a portion of a human body and examining the changes in those wavelengths and relating them to electrical signals to determine if a leak has occurred. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ infrared rays as the particular 'type' of electromagnetic radiation, at a specific wavelength (as recited in claims 13, 15 and 17), as taught by Atkins et al., modifying the leak detector disclosed by Dvorsky et al. and Condeva, thus providing a leak detecting device that will not be triggered by ambient noise, light and temperature changes nor by patient activities (Atkins et al.: col. 2, lines 33-36) during the examination of internal organs or otherwise.

Response to Arguments

5. Applicant's arguments filed 07 February 2008 have been fully considered but they are not persuasive. Applicant's main argument is that it would not have been obvious to one of ordinary skill in the art at the time the invention was made to "modify the Dvorsky leak detector by employing the Condreva technique of measuring the transit time of a pulsed sound wave signal to arrive at Applicant's claimed leak detector."

6. In response to applicant's argument that the Dvorsky and Condreva disclosures cannot be combined, or that it would not of been obvious to one having ordinary skill in the art at the time the invention was made to combine the two references, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, Dvorsky discloses a leak detector having most of the recited elements recited in claim 1, most particularly, the employment of sound (i.e. sonic/ultrasonic) waves/signals emitted towards a human body and subsequently, the reflection of those waves/signals are detected and/or measured. One having ordinary skill in the art is well aware of all the properties of waves/signals, especially acoustic/sound signals (pulsed or otherwise), including inherent aspects such as amplitude, wavelength, frequency and subsequent changes/alterations of these basic inherent properties due to reflection from a surface or propagation through different mediums, giving rise to alterations of these basic properties. This is clearly taught and disclosed in the Condreva reference (which discloses that it can be

employed in the field of medicine, thus well within the purview of one having ordinary skill in the art to make, use and combine with the Dvorsky reference) and furthermore provides an excellent motivation, that such teachings can be easily integrated in to existing systems.

7. Applicant further argues that the Condreva simply discloses a technique for detecting “impurities” in a pure sample and thus not the ‘measured’ sample. This is irrelevant, since, as pointed out above, one of ordinary skill in the art is well aware of the changes/alterations of the inherent properties of a wave/signal that arise in any type of sample, pure or otherwise. The Condreva reference clearly teaches that these alterations/changes are critical/important, and thus can be employed in any type of sample.

8. Lastly, the rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 159 6 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See also *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (setting forth test for implicit teachings); *In re Eli Lilly & Co.*, 902 F.2d reliance on legal precedent); *In re Nilssen*, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) (references do not have to explicitly suggest combining teachings); *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Int. 1985) (examiner must present convincing line of reasoning supporting the rejection); and *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Int. 1993) (reliance on logic and sound scientific reasoning). In the instant case, the scientific knowledge held by one having ordinary skill in the art at the time the invention was made would clearly enable one

of ordinary skill to employ the teachings of the Condreva reference (in particular, responses to changes/alterations in the basic/inherent properties of wave/signals) to modify the Dvorsky reference.

Allowable Subject Matter

9. Claims 2 and 3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Fitzgerald whose telephone number is (571) 272-2843. The

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examiner can normally be reached on Monday-Friday from 7:00 AM to 3:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams, can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/John Fitzgerald/
Examiner
07/20/2008
/Hezron Williams/

Supervisory Patent Examiner, Art Unit 2856